

inhibitor agent is a dye.

CB 51. A method according to claim 41<sup>53</sup> wherein the specific inhibitor agent is sulfobromophthalein.

Concl. 52. A method according to claim 41<sup>53</sup> wherein the specific inhibitor agent is oleic acid.

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REMARKS

Reconsideration is requested.

The objection to the drawings are noted. The submission of new formal drawings is requested to be held in abeyance pending allowance.

The Tables relating to the claimed subject matter have been replaced per the above. The other Tables and related text will be deleted upon an indication of allowance.

The claims are 41 to 52. This numbering tracks with the numeration employed in the Office Action.

The newly submitted claims are written around the Examples appearing in the specification at pages 24 et seq., and are directed to the testosterone assay.

The absence of salicylate, 2, 4-dinitrophenol and 8-anilino-1-naphthalenesulfonic acid (ANS) is disclosed at page 26, first full paragraph.

The calibrators of claim 42 and 49 are disclosed at page 25, 5th line et seq.

The antibody of claim 43 is disclosed at page 25, 1st line et seq.

The solid substrate (polypropylene) of claims 44 and 45 is disclosed at page 25, 3rd and 4th lines and page 26, last line.

The labeling of claim 46 is disclosed at page 24, 5th line from the bottom of the page.

The 6-hydroxytestosterone-19-carboxymethyl ether histamine of claim 47 is disclosed at page 24, 6th and 7th lines from the bottom of the page.

The pH 7.4 and temperature 37°C of claim 48 are disclosed at page 24, 3rd line from the bottom of the page and page 25, 13th line respectively. Also, original claims 20 and 21.

The dye sulfobromophthalein, claims 50 and 51, are disclosed at pages 25 and 26, Examples 1 and 2.

The oleic acid of claim 52 is disclosed at page 25, Table 25.

The various rejections under 35 US 112 do not apply to these claims.

The issue of new matter has also been rendered moot.

The prior claims were rejected on the basis of public use and sale of T3 and T4 assays, 35 USC 102, 103. However this may be, these assays are not anticipatory of testosterone assays.

Further, such T3 and T4 assays do not render obvious the subject matter of claims 41-52.

The claims were also rejected based on the Interference count in Interference No. 101933. As the Examiner notes, this count was general in nature. The instant claims are directed to particular testosterone assays as more specifically disclosed in the cited Examples.

The claims are not subject to rejection pursuant to MPEP 2363 Under MPEP 2363.03 at page 2300-34, where the Interference was terminated due to prior art and without award of priority, applicants "other" claims need to be reviewed to determine whether the other claims are patentable over the prior art which was the basis for the termination of the Interference. The novelty of the

particular testosterone assay of the instant claims was not destroyed by any prior use or sale of T3 or T4 assays in the sense of 35 USC 102.


Turning to 35 USC 103, the instant claims are directed to testosterone assays wherein salicylate, 2, 4-dinitrophenol and ANS must be avoided to prevent displacement of testosterone from albumin which results in a false "high" assayed value for free testosterone, all as detailed in Example 1, Specification at pages 25-26.

The avoidance of salicylate is directly contrary to the T3 and T4 assays of assignee Diagnostic Products Corporation relied upon to establish prior public use. These T3 and T4 assays contained salicylate, see the El Shami Declaration filed March 9, 1998. Thus, there can be no rejection under 35 USC 103.

The Corning "Immunophase" Free T4 assay product bulletin discusses, at page 10, the effect of Na salicylate on the displacement of labeled T4 analog from antibody. However, Corning was completely oblivious to any effect salicylate has on the displacement of anything from circulating proteins such as albumin. Thus, Corning does not suggest the present invention which is based on the discovery that salicylate must be avoided to prevent unwanted displacement of testosterone from albumin.

The Notice of Allowance is requested.

Respectfully submitted,

  
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